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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/071,541	05/04/1998	H.-J. SU HUANG	040750-5001	5607

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EXAMINER

MAIER, LEIGH C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/071,541

Applicant(s)

HUANG ET AL.

Examiner

Leigh C. Maier

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Status of the Claims

Claims 1, 7, 9, 11, 13, and 15 have been amended. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any objection or rejection not expressly repeated has been withdrawn.

Claim Rejections - 35 USC § 112

Claim 7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim now recites that the TK inhibitor is “selective” for a tumor specific mutant EGFR, amended from “relatively selective” in the previous version. As noted in the previous Office action, the present specification defines “relatively selective” at page 13, 2nd paragraph. However, the examiner does not find a definition that distinguishes “selective” from “relatively selective,” so that one of ordinary skill would not be apprised of the metes and bounds of the claim, rendering it vague and indefinite.

Claim Rejections - 35 USC § 102

Claims 1-4, 6, 7, and 9-15 are again rejected under 35 U.S.C. 102(b) as being anticipated by Tsai et al (Cancer Res., 1996) with Garcia de Palazzo et al (Cancer Res., 1993) to support inherency, as set forth in the previous Office action.

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Applicant's arguments filed September 13, 2004 have been fully considered but they are not persuasive. Applicant cites two portions of Tsai that purport to teach that the activity of the TK inhibitor is based on its effect on the wt EGFR. Both of these passages discuss the fact that AG825 selectively enhances that chemosensitivity of a cell line in proportion with the cell line's expression of p185^{neu}, the product of the gene HER-2/*neu*. Neither passage demonstrates the absence of a mutant EGFR gene. As discussed in the previous Office action, Applicant admits and de Palazzo teaches that mutant EGFR genes (type III, Δ EGFR) are expressed in many cases of lung cancer. If the gene is present, which based on Applicant's admission and teaching in the art appears more likely than not, the method is accomplished even if the reference does not recognize it at the time.

Claims 1-3, 6, 7, and 9-15 are again rejected under 35 U.S.C. 102(b) as being anticipated by Kufe et al (US 6,524,832), as set forth in the previous Office action.

Applicant's arguments filed September 13, 2004 have been fully considered but they are not persuasive. Applicant contends that the reference "goes to great measures to establish a relationship between the effect of the tyrosine kinase inhibitor and the expression of a wild-type EGFR." However, Applicant fails to cite any passage in the reference demonstrating such measures. Again, Applicant's admission and teaching in the art suggests the presence of mutant EGFR genes in cancerous cells, so the method is accomplished even if the reference does not recognize it at the time.

Claim Rejections - 35 USC § 103

Claims 1-16 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Nagane et al (Cancer Res., 1996) and Han et al (Cancer Res., 1996) in view of Kondo et al (Cancer Res., 1995), as set forth in the previous Office action.

Claims 1-16 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Nagane et al (Cancer Res., 1996) and Han et al (Cancer Res., 1996) in view of Kondo et al (Cancer Res., 1995) and further in view of Howell et al (US 5,597,798), as set forth in the previous Office action.

Applicant's arguments filed September 13, 2004 have been fully considered but they are not persuasive. Applicant states that "[i]t has been established that Nagane [sic] *et al.* is not available as prior art." The examiner respectfully disagrees. The Nagane reference that was made unavailable is reference C24: Nagane *et al.*, 1998, and the reference used in the current rejection is reference C25: Nagane *et al.*, 1996. The rejection is maintained for reasons of record.

Claims 1-16 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Kufe et al (US 6,524,832) in view of Wagner et al (Int. J. Cancer, 1996) and Han et al (Cancer Res., 1996), as set forth in the previous Office action.

Applicant provides no further argument to this rejection. The rejection is maintained for reasons of record.

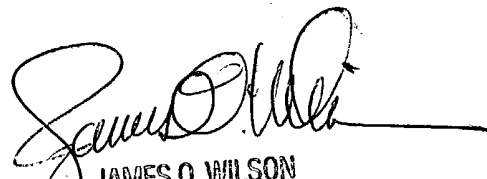
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Allowable Subject Matter

Allowable subject matter is as set forth in the previous Office action.

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
October 20, 2004